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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,001	04/21/2000	Joan C. Egrie	A-460A	1458

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/08/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/559,001

Applicant(s)

EGRIE ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of Application, Amendments and/or Claims

The amendment filed 26 August 2002 (Paper No. 15) has been entered in full. Claims 1-44 were cancelled. New claims 45-60 were added.

The information disclosure statement filed 15 October 2002 (Paper No. 17) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Withdrawn Objections And/Or Rejections

Upon further consideration the objection to the specification because of alterations which have not been initialed and/or dated as required by 37 CFR 1.52(c) as set forth at page 3 of the previous Office Action (25 February 2002, Paper No. 13) is *withdrawn*. The informality of the non-initialed alteration in the address is waived.

The objection of claims 28 and 31 under 37 CFR 1.75(c) as set forth at page 3 of the previous Office Action (25 February 2002, Paper No. 13) is *withdrawn* in view of the amendment (26 August 2002, Paper No. 15).

The rejection of claims 11-13, 15-17 and 24-26 under 35 U.S.C. 112, second paragraph as set forth at page 3 of the previous Office Action (25 February 2002, Paper No. 13) is *withdrawn* in view of the amendment (26 August 2002, Paper No. 15).

The rejection of claims 11-13, 24-26, 28 and 31 under 35 U.S.C. 102(b) as being anticipated by Elliott *et al.* (WO 95/05465, IDS#5, BC) as set forth at page 4 of the

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previous Office Action (25 February 2002, Paper No. 13) is *withdrawn* in view of the amendment (26 August 2002, Paper No. 15).

The rejection of claims 15-17 under 35 U.S.C. 103(a) as being anticipated by Elliott *et al.* (WO 95/05465, IDS#5, BC) in view of Yoshitomi *et al.* (US Patent No. 5,559,093) as set forth at pages 5-6 of the previous Office Action (25 February 2002, Paper No. 13) is *withdrawn* in view of the amendment (26 August 2002, Paper No. 15).

Claim Rejections - 35 USC § 112, written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-60 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "an analog of human erythropoietin comprising the amino acid sequence of human erythropoietin from residues 1-165 as shown in SEQ ID NO:1 **except** for....." (claims 45, 46, 49, 50), "the composition further comprising an amino acid" (claim 58) and "wherein the amino acid is lysine or glycine" (claim 59).

Applicant's amendment, filed 26 August 2002 (Paper No. 15), asserts that no new matter has been added. Applicant does not provide sufficient direction for the written description for the above-mentioned "limitations", therefore the exact wording or connotation of the instant claims are not readily apparent.

In addition, the recitation of "except for one or more amino acid changes", "except for the amino acid changes" and "except for Asn at position 30....." (claims 45, 46, 49 and 50) appears to be a negative limitation. Adding the expressed exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts. See Ex parte Grasselli, 231 USPQ 393 (BPAI 1983).

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Also, see MPEP 2163.05 Changes to the Scope of Claims; it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

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In re Smith, 173 USPQ 679; it was ruled that a genus may not support a subgenus even though there is a disclosed species within the genus. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Objections

Claims 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 46 is drawn to an analog comprising SEQ ID NO:1 except for one or more amino acid changes which provide for one or more additional glycosylation sites as compared to human erythropoietin wherein one additional site is introduced at positions 52, 53, 55, 86, or 114, however dependent claim 47 is drawn to the analog comprising glycosylation sites at positions 30, 55, 88 and 114.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
November 6, 2002



ELIZABETH SEMMER
PRIMARY EXAMINER